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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,661

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Kenneth Kao

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CANADA

EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,661	Applicant(s) KAO ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8,10,57-59,61,65-67 and 70-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,57,58,72-74,76 and 77 is/are allowed.
- 6) ☒ Claim(s) 8,10,59,61,65-67,70,71,75 and 78-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> |

DETAILED ACTION

1. Claims 1, 8, 10, 59, 61, 70, 71, and 75 have been amended.
Claims 3, 62, 64, 68, and 69 have been cancelled.
Claims 79-89 have been added.
2. Claims 1, 2, 4, 8, 10, 57-59, 61, 65-67, and 70-89 are under examination.
3. The following office action contains NEW GROUNDS of Rejection.

Objections Withdrawn

4. The objection to claims 3 and 69 is withdrawn in view of applicant's cancellation of the claims.

Rejections Withdrawn

5. The rejection of claims 1, 2, 4, 8, 10, 57-59, 61, 62, and 64-78 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendments to the claims.
6. The rejection of claims 10, 62, 64-68, and 78 under 35 U.S.C. 103(a) as being obvious over Kramps, et al. in view of Kennedy is withdrawn in view of applicant's amendment to the claims.

NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 8, 10, 59, 61, 65-67, 70, 71, 75, and 78-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 8, 10, 59, 61, 65-67, 70, 71, 75, and 78-89 are indefinite in the recitation “hPygo2 protein defined by...” the recited amino acid residues in SEQ ID No. 2. The phrase is indefinite because the exact meaning of the phrase is unclear and the term “defined” according to the Merriam-Webster online dictionary ([Merriam-Webster Online Dictionary](#). 2008.) means to determine or identify the essential qualities or meaning of, or to fix or mark the limits of. Thus, it is unclear if the recited amino acid residues of SEQ ID No. 2 define the sequences of the amino acid residues and are a required element of the claims or if the recited amino acid residues merely define the boundaries of the protein. Accordingly, the phrase “hPygo2 protein defined by...” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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- b. Claim 88 is indefinite for reciting the phrase “monoclonal antibody” in a claim dependent upon a claim that recites a “polyclonal antibody”. It is unclear how the antibody can be both a polyclonal and a monoclonal antibody.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 10, 65-67, 78, and 83-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isogai, et al. (US PAT 6,943,241, filed March 25, 2002) in view of Kennedy (US PG PUB 2001/0016651 filed January 31, 2001, as cited in the previous office action).

The claims recite a kit for determining the presence or absence of a cancer, wherein the cancer is at least one of cervical cancer, breast cancer, ovarian cancer and lung cancer, in a patient according to the method of claim 1, the kit comprising a reagent capable of detecting hPygo2 protein in a biological sample obtained from the patient, and instructions for using the reagent to determine whether the level of hPygo2 gene expression in the biological sample is higher compared to a predetermined cut-off value, wherein the predetermined cut-off value is the level of hPygo2 gene expression in a normal biological sample, and wherein the reagent is an antibody or fragment thereof that binds specifically to hPygo2 protein in the region defined by amino acids 89-328 of SEQ ID No. 2, and therefrom determining the presence or absence of cancer in the patient, wherein the cancer is ovarian cancer, and the biological sample comprises epithelial ovarian cells, wherein the cancer is breast cancer, and the biological sample comprises mammary cells, wherein the cancer is cervical cancer, and the biological sample comprises cervical cells, wherein the cancer is lung cancer, and the biological sample comprises lung cells, wherein the antibody or fragment thereof is a monoclonal antibody or fragment thereof, wherein the reagent is a polyclonal antibody that binds

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specifically to hPygo2 protein in the region defined by amino acids 89-328 of SEQ ID No. 2. The claims also recite an antibody or fragment thereof that binds specifically to hPygo2 protein in the region defined by amino acids 89-328 of SEQ ID No. 2, wherein the antibody is a polyclonal antibody.

Isogai, et al. teach a protein that is identical to the amino acids 160-406 of the instant SEQ ID No. 2. Isogai, et al. teach monoclonal and polyclonal antibodies that bind to the polypeptide for detection, diagnosis or protein purification (column 38 lines 30-57). Isogai, et al. do not teach the antibodies in a kit. This deficiency is made up for in the teachings of Kennedy.

Kennedy teaches supplying antibodies, polynucleotides, or polypeptides in a kit for detecting the presence of an expression product in a biological sample (paragraph 76).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the antibody to the polypeptide of Isogai, et al. in a kit as taught by Kennedy.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced the antibody of Isogai, et al. in a kit as taught by Kennedy because the polypeptide sequence of Isogai, et al. is identical to amino acid residues 160 to 406 of SEQ ID No. 2 and the claims recite an antibody that binds to residues 89-328 of SEQ ID No. 2. Thus the antibody of Isogai, et al. would bind to the instantly claimed hPygo2 protein. Further, it is routine in the art to supply reagents in the form of a kit. Additionally, Kennedy teaches an intended use of the kit for detecting expression products in a biological sample, and the intended use of the

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instant kit is to detect hPygo2 protein in a biological sample. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the antibody of Isogai, et al. in a kit in view of Kennedy.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the references.

Conclusion

13. Claims 1, 2, 4, 57, 58, 72-74, 76, and 77 appear to be in condition for allowance.

Claims 8, 10, 59, 61, 65-67, 70, 71, 75, and 78-89 are rejected.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 29, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643